TAB 5

510(K) SUMMARY

JUN 14 2010

Date of Submission	11/9/09
Official Contact / Address of Manufacturing facility	Matthew Young Manager, Quality Assurance and Regulatory Affairs Children's Medical Ventures 191 Wyngate Drive Monroeville, PA 15146 Phone: 724-387-4012 Fax: 412-380-8850 Email: matthew.young@philips.com
Proprietary Name	Oral/Enteral Syringes
Common/Usual Name	Gastrointestinal tubes and accessories
Classification Reference	21 CFR 876.5980
Classification	Class II
Appropriate Classification Panel	Gastroenterology / Urology
Product Code	FPD
Predicate Devices	Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944) Respironics, Inc. Enteral Only Extension Set (K082654)

Intended Use/Indications for Use

The Oral/Enteral Syringes is intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Only Syringes is disposable and for single patient use only.

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Oral/Enteral Syringes are substantially equivalent to the Respironics, Inc. Enteral Only Extension Set (K082654) and the Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944).

Design verification tests were performed on the Oral/Enteral Syringes as a result of the risk analysis and product requirements. The following tests were conducted:

- Volume Measurement Accuracy Testing
- Enteral Feeding Extension Set Interface Testing
- Size and Material Inspection
- Biocompatibility Testing
- Sterility Testing
- Reliability Inspection
- Labeling Inspection
- Environmental Operating Testing
- Storage Testing
- ISTA Testing

Testing Results demonstrated that the Oral/Enteral Syringes meet the required acceptance criteria. Children's Medical Ventures has determined that the Oral/Enteral Syringes are substantially equivalent to the predicate devices.

Device Description

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system. The Oral/Enteral Syringe barrels, plungers and end caps are comprised of Polypropylene, and the pistons are comprised of Silicone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6C
Silver Spring, MD 20993-0002

Philips Children's Medical Ventures
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUN 14 2010

Re: K100099
Trade/Device Name: Oral/Enteral Syringes
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: June 3, 2010
Received: June 4, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100099

Device Name: Oral/Enteral Syringes

Intended Use/Indications for Use:

Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100099